

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Takao KASAI et al.

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Art Unit: 3761

For: ABSORBENT ARTICLE

Examiner: M. M. Kidwell

DECLARATION PURSUANT TO 37 C.F.R §1.132

Commissioner for Patents
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Sir:

I, Takao Kasai, declare and say as follows:

1. I received my degree in 1989 from Kanazawa University Graduate School of Natural Science & Technology.
2. I joined Kao Corporation in 1989, working in the Research Laboratories. Since 1989, I have been involved in the research and development of nonwoven fabrics and films. Since 1995, I have been involved in the research and development of diapers. Since 2006, I have been involved in the research and development of materials for sanitary goods.
3. I am familiar with U.S. Application Serial No. 10/770,511, of which I am a co-inventor. The following experiments were conducted either by myself or under my supervision and control. These experiments demonstrate that the presently claimed absorbent article achieves unexpected and superior results over the article of Ducker '649 (U.S. 5,938,649). Further, these experiments clearly evidence that the use of the absorbent article of the present invention results in a significant decrease in diaper rash, whereas the use of the absorbent article of Ducker '649 does not exhibit any effect on diaper rash.

A. Comparative Testing

Comparative testing was performed to compare the absorbent article of the invention with an absorbent article similar to that disclosed by Ducker '649. The testing conditions and results of the comparative experiments are shown in Table 1 below.

Subjects wearing the absorbent article of the invention or the absorbent article of Ducker '649 were observed for determined periods of time (see Table 1). In reporting the results of the experiments, the average incidence of diaper rash was calculated by adding the number of times the subjects exhibited diaper rash over the evaluation period. The average incidence of rash is based on the total number of days in which all subjects used a diaper (for example, if subject "A" used diapers on 4 days, and subject "B" used diapers on 3 days, and subject "C" used diapers on 6 days, the "total number of days" is 13 days (4 + 3 + 6)). The number of times in which diaper rash was observed, the number of diapers used when the rash was observed, the total number of diapers used during the evaluation period and the total number of days evaluated are based on information recorded by the subjects' parents.

In order to verify the effect of the skin care agent, only the portion of the absorbent article where the surface sheet comes in contact with the skin was evaluated. Other portions, such as the gathering part and the anal area, were not evaluated.

As indexes for verification of the rash-prevention effect of the absorbent articles, the following values were used:

- i) Number of subjects exhibiting diaper rash / total number of subjects;
- ii) Incidence of diaper rash = Total number of times in which diaper rash was observed / total number of diapers used during the evaluation period;
- iii) Average Incidence of diaper rash (times/subject/week) = Total number of times in which diaper rash was observed / total number of subjects / total number of days in which all subjects used

diapers, and wherein the obtained average value (times/subject/day) is converted to an average weekly value (times/subject/week).

B. Results and Discussion

Table 1

Sample	Example 1 (article of the present invention)	Comparative Example 1 (corresponding to Ducker '649)
Subjects	Babies using M size baby diapers	Babies using M size baby diapers
Water-soluble skin care agent	Hamamelis extract 1%	Hiba extract 1%
Oily skin care agent	Diamide derivative	Wax, ester oil and petrolatum
Auxiliary agent	None; unnecessary	Surfactant; necessary to mix water with oil
Method of applying skin care agent	The diamide derivative was applied on a predetermined region of a sheet or absorbent article to be contacted with the skin of a wearer, on which the Hamamelis extract was applied	Hiba extract, wax, ester oil, petrolatum and surfactant were mixed, and then the mixture was applied on the surface of the diaper to be contacted with the skin of a wearer
Application amount of skin care agent	10g/m ² in total	10g/m ² in total
Method of recordation	<p>- The number of diapers used was not limited. Diapers were used as usual for each subject. The date of use, condition of the diaper and diaper rash presence and area affected were recorded at the time of diaper changes.</p> <p>- In determining the presence of diaper rash, visual observation was conducted by subjects' parents as described below.</p> <p>Condition of diaper rash</p> <ul style="list-style-type: none"> i) The skin is slightly red. ii) The skin is obviously red. iii) Rashes are observed on the skin. iv) The skin peeled off. v) Other 	<p>Condition of diaper rash</p> <ul style="list-style-type: none"> i) The skin is slightly red. ii) The skin is obviously red. iii) Rashes are observed on the skin. iv) The skin peeled off.
	<p>Observation areas</p> <ul style="list-style-type: none"> i) Stomach area ii) the vicinity of urination area iii) thigh area iv) hips v) anal area vi) back 	<p>Observation areas</p> <ul style="list-style-type: none"> i) Stomach area ii) the vicinity of urination area iii) inner thigh area iv) outer thigh area v) hips vi) anal area vii) back

Results			
Average incidence of diaper rash	Diapers with no skin care agents	Average incidence: 30 times/14 subjects/two weeks (i.e., the number of times of incidence of diaper rash was 30, including re-incidence)= 1.1 times/subject/week.	Average incidence: 1 time/5 subjects/16 days= 0.4 times/subject/week
	Diapers with skin care agents	Average incidence: 13 times/14 subjects/two weeks= 0.4 times/subject/week.	In four out of five people, the rash was observed. Average incidence: 9 times/5 subjects/32 days= 2 times/subject/week
Number of diapers used when the rash was observed	Diapers with no skin care agents	278 out of 1167 diapers	1 out of 69 diapers
	Diapers with skin care agents	131 out of 1290 diapers	61 out of 142 diapers

The above results evidence that the incidence of diaper rash is reduced by more than half when utilizing the novel absorbent article of the invention versus the article of Ducker '649.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Takao Kasai
Signature

Takao Kasai
Takao Kasai

April 10, 2008
Date